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THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION

March 6, 2000

E. EDWARD KAVANAUGH
PRESIDENT

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Charles J. Ganley, M.D.
Director
Division of OTC Drug Products (HFD-560)
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Food and Drug Administration
9201 Corporate Boulevard
Rockville, Maryland 20850

Re: Final Regulation for Sunscreen Drug Products (Docket No. 78N-0038)

Dear Dr. Ganley:

This submission is made in response to the Food and Drug Administration's request from the October 26, 1999 Sunscreen Working Group Meeting and industry's commitment to provide the methods validation material on the two sunscreen control standards. Enclosed please find the method validation package for the HPLC assay for the SPF 4 and SPF 15 standard lotions.

Under separate cover, we are providing Dr. Wilson DeCamp three review copies and a desk copy addressed to his attention. We look forward to continued discussions with the Agency to resolve the technical issues associated with this rulemaking.

Respectfully submitted,

Beth Anderson

Elizabeth H. Anderson
Assistant General Counsel

attachment

cc: Dr. Wilson DeCamp (with attachment)
Dockets Management Branch (HFA-305) (with attachment)

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